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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶:

A61F 5/48

(11) International Publication Number: WO 96/14813

(43) International Publication Date: 23 May 1996 (23.05.96)

(21) International Application Number: PCT/AU94/00697

(22) International Filing Date: 11 November 1994 (11.11.94)

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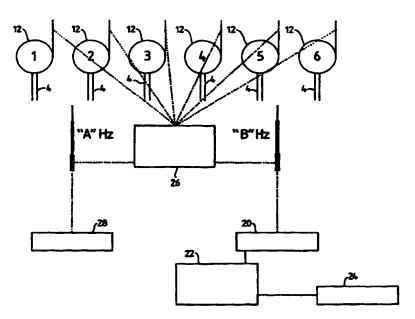
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(81) Designated States: AM, AT, AU, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, JP, KE, KG, KP, KR, KZ, LK, LR, LT, LU, LV, MD, MG, MN, MW, NL, NO, NZ, PL, PT, RO, RU, SD, SE, SI, SK, TJ, TT, UA, US, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG), ARIPO patent (KE, MW, SD, SZ).

Published

With international search report.

(54) Title: INCONTINENCE MANAGEMENT SYSTEM



(57) Abstract

A monitor for use in hospitals, nursing homes and the like, to receive and record signals, from a plurality of sensors (4), of urinary and/or faecal incontinence in a corresponding number of patients to show when attention is required and to indicate, in respect of each patient, such pattern or regularity of such condition as may assist in the perception of the needs of that patient and, therefore, in the management of the condition and the efficiency of running of the establishment as a whole. The sensors (4) when activated in the presence of moisture send respective signals to a receive station (20) via a booster station (26). The time and sensor number(s) are recorded by a processor (22) and/or printer (24). A second signal may be transmitted by the booster (26) to a page (28) for staffing assistance.

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INCONTINENCE MANAGEMENT SYSTEM

This invention relates to an incontinence monitoring system and is particularly concerned with a system for the detection 5 monitoring and management of urinary, faecal and other forms of incontinence, in hospitals, nursing homes, geriatric institutions, private homes, gardens and suchlike places where, unchecked, such conditions can give rise to discomfort or at least embarrassment for the patient, an unpleasant odour and environment for others in the vicinity, and considerable expenditure of human and financial resources due to the need for checking and, where necessary, changing and cleaning bed-linen and clothes.

Health regulations or recommendations may prescribe a maximum period e.g. 15 minutes for which a patient can be left in a wet state. In the past, in order to ensure both reasonable comfort for incontinents and compliance with prevailing regulations or normal practice it has generally been necessary for nursing staff manually to check every patient at least once in the prescribed period. Quite apart from the unpleasantness, for nursing staff, or skin contact with patients' urine or faeces, such a regimen can be a severe strain on staff resources and an often unnecessary interruption to patients' sleep.

It is an object of the invention to alleviate one or more of the above disadvantages.

30 According to the present invention there is provided an incontinence monitoring system for use in a hospital, nursing home or suchlike location, the system comprising a plurality of sensors and a monitor to receive and record signals from the sensors, each sensor being adapted to be associated with a respective person and being responsive to urinary and/or faecal incontinence in that person, the monitor being capable of recording the time of onset of each incontinence condition and of indicating any regularity or pattern of incontinence in each said person.

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By detecting and recording, for a particular patient, any incontinence pattern rhythmicity or regularity, this can be used as a basis for predicting the likelihood of that patient being in a wet or dry state at a particular time, and preferably forestalling such an event to enable the patient to receive appropriate and timely attention such as "toileting" e.g. by commode or bedpan.

The monitor may include a processor and a receiver adapted to receive and discriminate between signals from the respective sensors.

Advantageously, the monitor includes display means for indicating said signals to an operator.

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In a preferred embodiment the monitor includes a radio receiver and each sensor includes a transmitter adapted to emit a radio signal. The monitor may include a booster to boost the radio signals received thereby.

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Advantageously, the monitor includes means for transmitting the signals or further signals responsive to the signals to one or more pager units.

25 Each sensor may comprise a flexible band comprising an insulating mounting for spaced conductor strips, the band being adapted to be located in a moisture-absorbent pad or garment to be worn by the patient so that at the onset of a wetting episode the moisture completes an electric circuit 30 between said strips and triggers the signal to the monitor.

More generally, in one embodiment, a sensor/transmitter for each patient (or other person to be monitored) may include an e.m.f. source such as a battery for a signal transmitter and a sensor wired in circuit therewith and responsive to a condition the onset of which a warning is required.

The sensor may include two terminals between which is a

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moisture - receptive strip or pad of which the electrical conductivity is substantially zero in the normal or dry state but increases sharply when moistened by even a small amount of urine. The sensor therefore may act as a switch to pass voltage/current to the signal transmitter, which may be in the form of a small wireless transmitter, at the onset of, for example, urination.

The signal can be transmitted as or via a coded radio signal to a receiver which could be located in a nurses' station or central office. Associated with the receiver may be a microprocessor which interrogates the receiver (1) to determine or confirm that an alarm has been triggered and (2) to identify the relevant patient, with a computer (such as a standard 386 with e.g. a 40 megabyte hard disk) arranged to operate on a program specially dedicated to the purpose of recording data for each of up to e.g. 48 patients.

The sensor band may be a re-usable strip attached to a nappy or other moisture-absorbent pad suitably worn to detect the presence of urine. It may be secured using a piece of medical tape or placed in a pocket. Strips could be recovered by arrangement with a laundry service. If the garment to which it is attached is disposable, the strip could be recovered by a staff member for cleaning "in house".

In order that the invention may be better understood reference will now be made, by way of example only, to the accompanying drawings which are to be considered as part of this specification and read herewith. In the drawings:

Figure 1 is a diagram showing a practical embodiment of the invention in schematic form:

Figure 2 shows a detector band sensor and insertion tool for use with the invention as illustrated in Figure 1; and

Figure 3 shows a moisture absorbent pad capable of receiving a sensor by the means shown in Figure 2.

The practical embodiment of the invention as shown in the

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drawings, including the operation thereof, will now be described.

Figure 1 shows a monitor for only six patients. This is 5 merely for convenience of illustration. It is envisaged that a much larger number could be monitored by the one device.

A master station 20 receives signals, via a suitable antenna, from patient transmitters up to 250 metres distant. The station may have an associated personal computer ("PC") 22 or, for example, may be connected direct to a printer 24.

Each patient has a code. The station may be powered from 240V AC mains supply reduced to 12V with battery back-up (not shown) in case of mains failure. The battery may be "trickle-charged" in known manner. Setter buttons may be provided to record time, day, month, year and "re-set". If a personal computer is used, such controls may not be required if software allows for setting.

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In lieu of or in addition to a PC monitor, a 3-4 digit Alpha numeric light emitting diode ("LED") (not shown) may display patient numbers and "low-battery" indication thereafter. Simultaneous "alerts" may be sorted out by arranging for the display to repeatedly "scroll" through alert numbers in succession, dropping off each number as the relevant patient is attended to. Where no PC is provided, the data may be recorded by the directly-connected printer.

30 The master station 20 is operated by connecting a printer 24 or PC 22, setting the date and time, and noting and acting upon "alerts" as they are recorded. Over a period of time, for example 1 or 2 weeks, any pattern or regularity of incontinence periods for a particular patient may be identified from the recorded information, either manually or using appropriate software, and the patient, or nursing staff, may be arranged to anticipate an oncoming period of incontinence.

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A booster, repeater and/or page unit 26 may be associated with the master station unit. It can be adjusted to receive one frequency e.g. 27 MHZ and boost the signal to the master station should circumstances so require. A different frequency e.g. 150 MHZ could be used to transmit a signal to a pager 28 to call a staff member for assistance. A booster may boost the signal to the pager. Antennas and suitable connectors may be installed for both or all relevant frequencies.

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Figure 2 illustrates an elongate sensor or detector band 4 and an applicator tool 5 for inserting band 4 into a nappy-type moisture absorptive pad 6 (Figure 3) adapted to be worn by the patient. Band 4 may include a pair of spaced electrically conductive strips 7,8 of silver or other suitable material mounted on a length of polyester or other suitable insulating material. The top surface of each strip may be coated e.g. with carbon to prolong life of the strip. Strips 7, 8 are suitably positioned as to contact and to be conductively bridged and thereby short-circuited by wetting of the pad 6 into which the band has been inserted, due care having been taken to ensure that the "conductive" side of the band i.e. the side to which strips 7, 8 are affixed, is in contact with the pad itself.

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Band 4 has a forward end portion 9 receivable into spring clip 10 of tool 5. At the "rearward" end of band 4 is a connector element 11 whereby strips 7, 8 are placed in circuit with transmitter unit 12 (Figure 3).

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The detector band (Figure 2) is fitted to the pad (Figure 3) as follows: the forward end portion 9 of a dry band 4 is inserted into spring clip 10 of the applicator tool. Pointed end 13 at the same end of the tool as clip 10 is used to puncture an eternal waterproof plastics or like lining 14 of pad 6 about 60 to 80 mm in from the edge as shown in Figure 3. The tool 5 with band 4 in train is then pushed inwards along the centre line of pad 6, just separating the lining

from the absorbent material with the strips 7, 8 facing away from the lining and towards the absorbent material.

When the band is fully inserted, connector 11 is held 5 independently of the tool which is pushed further in so as to disengage band 4 from clip 10.

Tool 5 is then turned 180° about its longitudinal axis so that it can be withdrawn without the clip 6 catching the 10 band. Band 4 now having been suitably located with conductive strips 7, 8 thereof facing the absorbent material of pad 6, tool 5 is withdrawn, leaving band 4 in place.

Transmitter 12 can be fitted to pad 6 using chrome clasps 16, as shown in Figure 3, with appropriate electrical connections to strips 7, 8 shown schematically at 17 via connector element 11.

The pad/transmitter assembly is now ready for fitting to the 20 patient.

Rather than being inserted and attached to pads such as 6, a sensor band or unit could be incorporated into e.g. a disposable paper garment or an underblanket or mat such as by printing or stitching, with suitable means for connection to a separate transmitter.

The transmitter 12 should be as small as possible. An LED may show when it is activated and may stay on until band 4 is removed from a moisture zone thereby concluding an "episode".

The transmitter may be powered by a re-chargeable NiCd battery.

35 A low power battery signal may report to both master display and pager (Figure 1).

The transmitter may be operated as follows: open the

transmitter unit 12; select a patient code number e.g. Mr Smith 007. (If a computer is used the patient code is keyed in); install the battery, close the transmitter unit, and attach unit 12 to pad 6 as already described with strips 7, 8 suitably connected.

When an "episode" occurs the transmitter LED illuminates and a signal is transmitted to the booster station 26. The booster repeats the signal, at frequency "B" (see Figure 1) to the master station 20 which displays "007" - for the duration of the episode. The printer 24 records "007" on a date/time basis as may the PC 22.

The booster 26 sends also a signal of frequency "A" to the 15 pager 28 to alert the nurse. The signal identifies "007" alert, and optionally also the time and date, on the pager display. The nurse acknowledge the message on the pager. Only one signal need be sent to the pager.

The nurse attends to the patient, disconnects the transmitter and fits a new absorbent pad. The transmitter is reconnected ready for the next episode. The pager memory can now be cleared, because data of the episode will have been recorded by the master station printer and/or computer.

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It will clear that especially in the case of bed-ridden patients, rather than by radio, signals could be sent through an electric wiring system from a transmitter at the bedside and only a sensor/pad component connected to the wiring need 30 be attached to the patient.

In some cases signals could be sent by wire (as distinct from radio) through the same or similar system to that used e.g. with a nurse call button.

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Also the invention can evidently be applied to the unconscious, semi conscious, paralyzed, part-paralyzed or confused, or any other patient who may be unable to initiate

a signal.

Furthermore it will be clear that the invention, in its "radio" form, is applicable to patients who are free to move around and even outside a building. Appropriate circuitry may provide an indication of the wearer's location (distance and direction) relative to a datum point, including an alarm should the wearer stray beyond a prescribed boundary.

10 Those skilled in the art will appreciate that the invention variations susceptible to described herein is modifications other than those specifically described. It is to be understood that the invention includes all such variations and modifications which fall within the its spirit The invention also includes all of the steps, 15 and scope. features, compositions and compounds referred to or indicated in this specification, individually or collectively, and any and all combinations of any two or more of said steps or In particular it will be appreciated that a features. 20 further aspect of the invention may be directed to all or any of the described features of the sensor, pad, mat and/or locating tool.

CLAIMS: -

- An incontinence monitoring system for use in a hospital, nursing home or suchlike location, the system comprising a plurality of sensors and a monitor to receive and record signals from the sensors, each sensor being adapted to be associated with a respective person and being responsive to urinary and/or faecal incontinence in that person, the monitor being capable of recording the time of onset of each incontinence condition and of indicating any regularity or pattern of incontinence in each said person.
- A monitoring system as claimed in claim 1 wherein the monitor includes a processor and a receiver adapted to
 receive and discriminate between signals from the respective sensors.
- A monitoring system as claimed in claim 1 wherein the monitor includes display means for indicating said signals to
 an operator.
 - 4. A monitoring system as claimed in claim 3 wherein the display means include an alpha numeric LED capable of displaying code indicia for each said person.

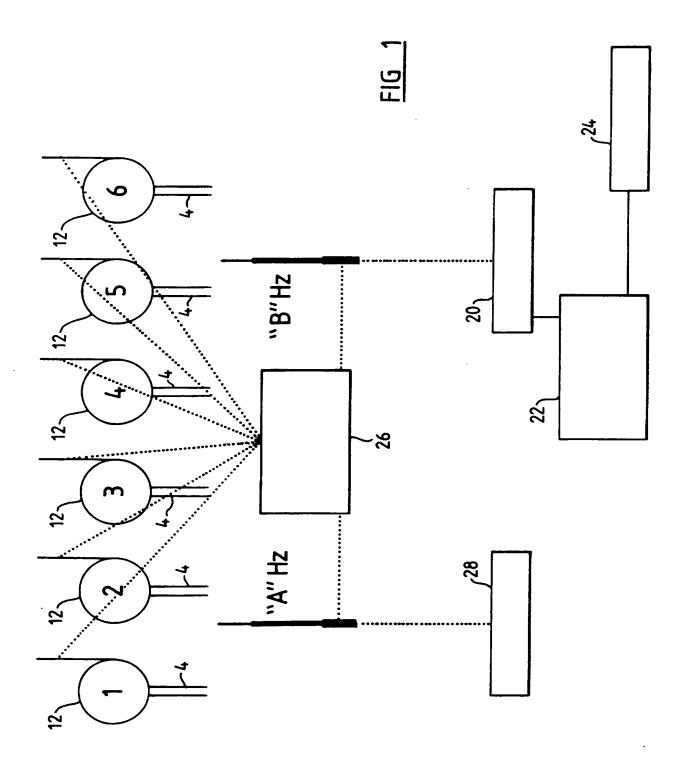
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- 5. A monitoring system as claimed in claim 1 wherein the monitor includes a radio receiver and each sensor includes a transmitter adapted to emit a radio signal.
- 30 6. A monitoring system as claimed in claim 5 wherein the monitor includes a booster to boost the radio signals received thereby.
- 7. A monitoring system as claimed in claim 1 wherein the 35 monitor includes means for transmitting the signals or further signals responsive to the signals to one or more pager units.

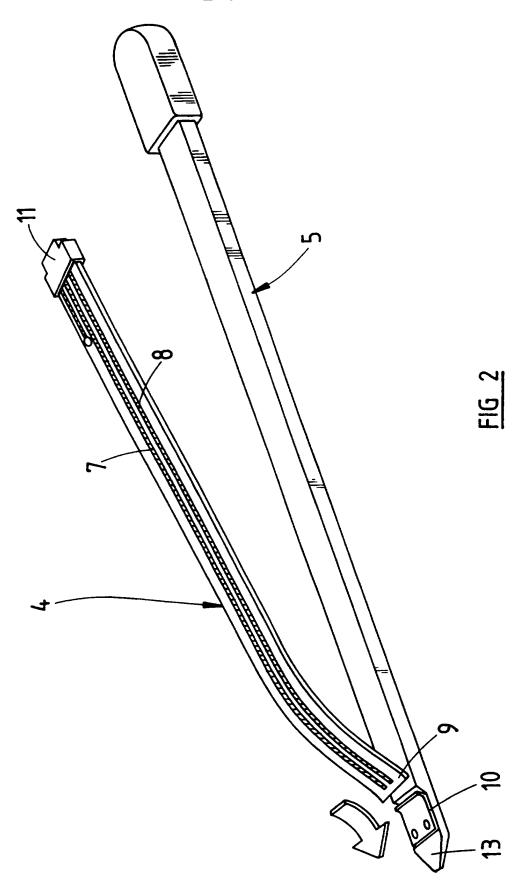
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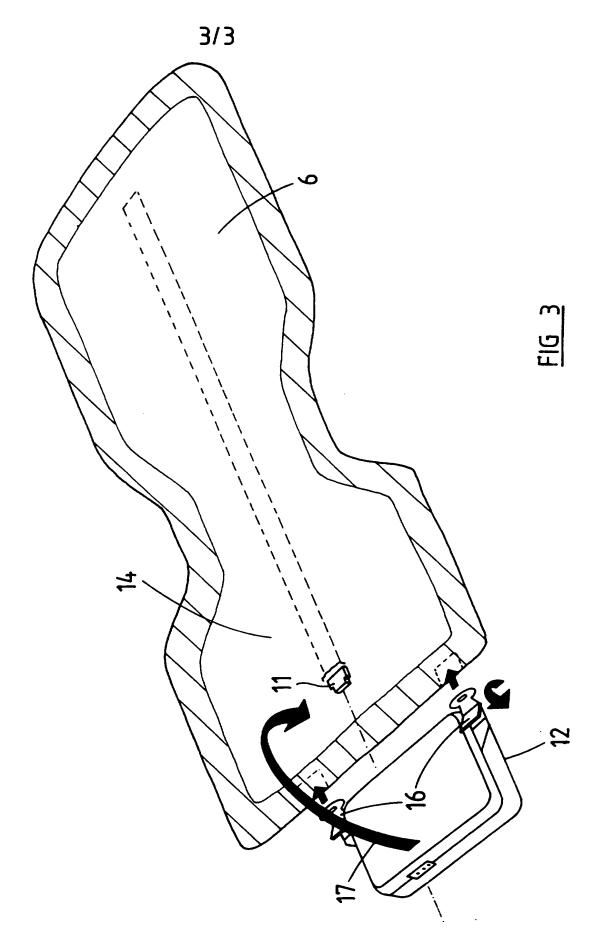
8. A monitoring system as claimed in claim 1 wherein each sensor is a flexible band comprising an insulating mounting for spaced conductor strips, the band being adapted to be located in a moisture-absorbent pad or garment to be worn by the patient so that at the onset of a wetting episode the moisture completes an electric circuit between said strips and triggers the signal to the monitor.







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INTERNATIONAL SEARCH REPORT

A. Int. Cl. ⁶ A ⁶	CLASSIFICATION OF SUBJECT MATTER					
According to	International Patent Classification (IPC) or to both	national classification and IPC				
В.	FIELDS SEARCHED					
	cumentation searched (classification system follow 5,48, 5/44, A61F 13/42, 13/44	ed by classification symbols)				
Documentation AU : IPC a	on searched other than minimum documentation to s above	the extent that such documents are included in	n the fields searched			
Electronic data base consulted during the international search (name of data base, and where practicable, search terms used) JAPIO DERWENT: monitor: or sens: or alarm						
C.	DOCUMENTS CONSIDERED TO BE RELEV	ANT				
Category*	Citation of document, with indication, where	appropriate, of the relevant passages	Relevant to Claim No.			
Y	US,A, 5137033 (NORTON) 11 August 199 See col. 3 lines 55-66	92 (11.08.92)				
ХY	US,A, 5074317 (BONDELL et al) 24 Dece See col. 6 lines 15-27	mber 1991 (24.12.91)				
A	EP,A, 270048 (STEGAT) 8 June 1988 (08. WO, 86/04710 (RADAKOVIC) 14 August					
Α						
Further in the	er documents are listed continuation of Box C.	X See patent family annex	•			
-	1 categories of cited documents :	"T" later document publisher filing date or priority da with the application but	d after the international te and not in conflict			
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"P" exhibition or other means document published prior to the international filing date but later than the priority date claimed		inventive step when the with one or more other s combination being obvio	document is combined			
		"&" document member of the	e same patent family			
	nual completion of the international search 1995 (21.02.95)	Date of mailing of the international search r 24 Feb 1995 (2	eport 4.02.95)			
Name and mai	ling address of the ISA/AU	Authorized officer				
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Facsimile No.	06 2853929	Telephone No. (06) 2832072				

INTERNATIONAL SEARCH REPORT

C(Continual	Citation of document, with indication, where appropriate of the relevant passages	Relevant to Claim No.
	FR, 2529080 (LERNOULD) 30 December 1983 (30.12.83)	
A	1 K, 232,000 (SEKNOOLD) 30 Secular 1703 (30.12.03)	
A	DE,A1, 2807538 (SCHLENKE) 23 August 1979 (23.08.79)	
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This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

	Patent Document Cited in Search Report				Patent Family	Member	
us	5137033						
US	5074317						
EP	270048	DE	3640900				
wo	86/04710	AU EP	53923/86 211874	CH GB	676060 8606416	DE	3603993
FR	2529080						
DE	2807538						

END OF ANNEX